

# Surviving Internal Auditing

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# Surviving Internal Auditing

Once you've got to grips with the main requirements of ISO 9001, you need to understand how to get the best from internal audits.

One of the requirements of ISO 9001 is that you 'shall conduct internal audits at planned intervals to determine whether the quality management system (QMS) conforms to the requirements of ISO 9001 and to the requirements established by the organization; and is effectively implemented and maintained.'

# Surviving Internal Auditing

In order to meet and satisfy this requirement, organizations must continually review their QMS to:

- ensure its continuing suitability and success
- reveal defects, danger spots or irregularities
  - suggest possible improvements
    - eliminate wastage or loss
- check the effectiveness of management at all levels
- be sure that managerial objectives and methods are effective and can achieve the desired result

# Surviving Internal Auditing

With the publication of ISO 9000, auditors now have to demonstrate their competence in more areas than before. Priorities now are not only on the structure, content and terminology of the revised standards, but also on the underlying quality management principles.

This means that auditors are now required to understand the organization's activities and processes. In addition, they must be able to appropriately audit against the requirements of the standard in relation to the organization's objectives.

# Surviving Internal Auditing

As a minimum, auditors must demonstrate  
competence in:

- the requirements of ISO 9001
- the concepts and terminology of ISO 9000
- the eight quality management principles,

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The eight quality management principles, namely:

- customer focus
  - leadership
- involvement of people
  - a process approach
- a system approach to management
  - continual improvement
- a factual approach to decision-making
- mutually beneficial supplier relationships

# Surviving Internal Auditing

- They should also show a general understanding of the performance improvement guidelines of ISO 9004, and a familiarity with the latest draft of the auditing guidance standard ISO 19011.

# Surviving Internal Auditing

- Auditing generally follows a linear process starting with establishing the criteria against which you are auditing and leading to a report concluding whether the criteria is being met. Should the audit find problems with the performance of a process, then you will implement corrective action aimed at preventing recurrence.

# Surviving Internal Auditing

- Purpose of an audit
  - The primary purpose of an audit is to enable organizations to evaluate their process management systems, determine deficiencies, and generate cost effective and efficient solutions. An audit is performed to check practice against procedure, and to thoroughly document any differences.
- Essentially, it is used to measure an organization's ability to do what it says it is going to do

# Internal Audit

The type and content of any first party internal quality audit will vary according to the size and activities of the organization. Its purpose is to:

- identify potential danger spots
  - eliminate wastage
- verify that corrective action has been successfully achieved
- provide a comparison between the QMS objectives and what is actually being done
  - confirm that everything is working efficiently
- identify non-compliance with previously issued instructions
  - identify deficiencies within the QMS
- recommend any corrective actions that could improve the system

# Internal Audit

- To meet these aims, the auditor must prepare an audit plan to determine whether the QMS is effectively achieving its stated objectives. It should be established as soon as possible and the procedures with which to carry out these audits should always be documented and available.

# Internal Audit

- To be effective, an internal audit should always include members of the organization's quality control staff, (provided that they are not responsible for the quality of that particular product). Normally these internal audits will be scheduled every three months or so.

# Internal Audit

Ideally, the audit should be pre-planned so that it covers all aspects of quality control within one calendar year. The audit plan should:

- cover the specific areas and activities that are to be audited
  - stipulate the reasons why an internal audit is being completed, e.g. organizational changes, reported deficiencies, survey or routine check
- stipulate the minimum qualifications of the personnel who are to conduct or assist with the audit
  - describe how the audit report should be finalized and submitted

# Internal Audit

- It is essential that management takes timely corrective action on all deficiencies found during an internal audit. Sometimes this can mean having to review the control methods used to indicate or predict the need for corrective action. Follow up actions should include the verification of the implementation of corrective action and the reporting of verification results.

# Audit Schedule

- Internal quality audits are usually planned and initiated by the quality manager. They will relate to the status and importance of the activities involved in a section or deliverable from your business. For large organizations, it would be quite normal for each department and section to be subject to at least three complete quality audits a year.

# Audit Preparation and Organization

- Depending on the complexity and the size of the audit, the quality manager may perform the audit himself, or (if sections are too large) he can assign a lead auditor and a team of auditors to complete the task.

# Audit Preparation and Organization

The quality manager or lead auditor is then responsible for organizing an agenda which will include the:

- scope and objectives of the audit
- people having direct responsibilities for the procedures to be audited
  - reference documents
- name of lead auditor and names of assigned auditors
  - date when the audit is to be concluded

# Audit Preparation and Organization

- Following a review of earlier audit reports on the same section or subject, the assigned auditors will prepare an audit checklist containing all the items to be covered, together with an audit program.

# Audit Execution

An initial meeting between the auditors, the auditees and the quality manager is held during which:

- a brief summary of the methods and procedures to be used for the audit is given
- the method of communication between auditors and auditees is agreed
- the audit program is confirmed

# Audit Execution

- In accordance with ISO 9001, all organizations are required to have a documented procedure for conducting internal quality audits. Normally this procedure will distinguish between two kinds of internal quality audits, being 'standards audit' and 'procedures audit'. The standards audit evaluates how well ISO is being applied, while the procedures audit evaluates how effective the organization's quality procedures, policies and instructions are.

# Audit Execution

Using the standards audit, the auditor will begin collecting evidence of compliance by interviewing personnel, reading documents, reviewing manuals, checking records and data, observing activities and studying working conditions.

As the evidence is collected, the auditor will answer each audit question and record his observations in this format:

- 'yes' means that this activity is in compliance with the standard
  - 'no' means that this activity is not in compliance
- 'not applicable' means that this question is not applicable in this situation

# Audit Execution

Once the auditor has completed the audit questionnaire, he will make a list of all the non-conformities and summarize his evidence.

Similarly, using the procedures audit, each applicable quality procedure, policy, plan and work instruction will be looked at. The following questions should be asked: is it documented? Is it being followed? Is it effective? Based on the evidence collected, the auditor will record his observation:

# Audit Execution

- 'yes' means that this activity is in compliance
  - 'no' means that this activity is not in compliance

Auditors will record all their observations on an audit observation sheet and all non-conformities will then be listed on a non-conformity worksheet which will eventually form part of the final audit report.

# Summarize Audit Results

- Auditors will then meet to discuss all their observations – particularly any non-conformities – with the quality manager.
- All observations of any non-conformities must be formally acknowledged by the manager responsible for the activity being audited.

# Summarize Audit Results

A closing meeting of auditors, auditees and the quality manager will then be held during which:

- audit observations will be clarified
- the critical significance of observations will be presented
  - conclusions drawn about compliance will be presented
- system effectiveness in achieving the quality objectives will be presented
  - corrective actions will be agreed
- the date for completion of the audit report will be agreed
- Minutes of all relevant meetings, decisions and agreements must be attached to the audit report.

# Preparation of Audit Report

The lead auditor now needs to prepare an audit report using an audit report form. The report must be signed by all members of the audit team, plus the quality manager, and copies sent to auditees and company management as required.

The report will list all non-conformities discovered, observations made and any conclusions drawn. It will also detail (in the summary) recommendations for correcting or preventing non-conformities and for making improvements.

# Corrective Action

- After the closing meeting, the lead auditor will prepare a 'corrective action request' for each agreed point. Corrective action requests should always state who is responsible for carrying out the corrective action and the timescale for its completion.

# Take Remedial Action

- The section or department which has been audited is then responsible for ensuring the agreed corrective actions are implemented. In addition, any observations, comments and recommendations made by the audit team must be taken into account.

# Follow Up

- Finally, the lead auditor is then responsible for ensuring that corrective action has been carried out and for notifying the quality manager of the status and completion of corrective actions.

# Types of Audit

## **Quality system audit:**

- An overall measurement of an organization's capability to meet the requirements of a standard

## **Management audit:**

- Checks to see if a business's strategic plan reflects its business objectives and has met the requirements of the intended market

# Types of Audit

## **Process audit:**

- Focuses specifically on single processes to verify that they are capable of delivering the necessary outputs

## **Procedural audit:**

- verification that documented practices are sufficient to ensure the implementation of approved policies and can control operations

## **System audit:**

- Ensures a business management system is sufficiently comprehensive to control all of the activities within that business

# Internal Audit Interview Techniques

- Give auditees credit
  - Auditees probably won't be quoting text verbatim from a procedure. They should be describing their process in a way that lets you understand it, and that demonstrates how well they understand it.
- Ask open-ended questions

# Internal Audit Interview Techniques

- Give the auditee an opportunity to explain what she does. The person will provide more complete information if she isn't being steered towards the auditor's preconceived notion of what the answer should be.
  - Ask how the auditee does his job
- You're not just trying to verify that something is done; you want to verify that it's done correctly – as defined.
- Reading a report on non-conforming product will tell you something wasn't done right, but assessing the process will help you pinpoint what went wrong.

# Internal Audit Interview Techniques

- Use documents
  - Remember to use documents to help you frame your question. This lets you determine if the documentation accurately reflects the requirements of the process.
  - Don't be afraid to repeat your question

# Internal Audit Interview Techniques

- Sometimes you need to come at a subject from a different angle.
- Restating a question helps the auditee to grasp what you're trying to ascertain.
- Give time for answers
- Be patient. The process owner may be thinking. Don't assume that a delayed response is an indication that the person is lying.
- Avoid jargon

# Internal Audit Interview Techniques

- Avoid quality speak. If you're trying to determine what the output of a process is, simply ask, 'What happens next?'
- Imagine different scenarios Suggest a scenario and ask: 'What would happen if...?' This will help verify how well the process is controlled if there is a deviation or something goes wrong. It will also help you assess the effectiveness of communication and the definition of responsibility.
  - Ask why

# Internal Audit Interview Techniques

- People who do tasks mindlessly, without understanding the reason for the activity, are less likely to be diligent in ensuring that the process is consistently and correctly implemented.

- Listen

- Are you hearing what the person is saying, or what you anticipate her answer to be? Look directly at the person who's speaking to maintain your own focus and look interested.

- Write it down

# Internal Audit Interview Techniques

- Record the evidence you've assessed. This provides the foundation for the audit report and it also allays any confrontation.
  - Explain what will be reported
- Always make sure you tell the auditee if you're planning to report a non-conformity uncovered in his area. No one likes to be blindsided two days after an audit by a report that appears to say that he made a mistake. Provide reassurance that the intent is to make the process better for everyone.

The End.

Questions???